



Patent
Attorney's Docket No. 010091-001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
C. Richard SCHLEGEL et al) Group Art Unit: 1813
Application No.: 08/216,506) Examiner: A. Caputa
Filed: March 22, 1994)
For: PAPILLOMAVIRUS VACCINE)

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**INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER**

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for
the above-identified patent application.

- ☐ No additional fee for submission of an IDS is required.
- ☒ The fee of \$210.00 as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A certification under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A certification under 37 C.F.R. § 1.97(e), a petition requesting consideration of
the information disclosure statement, and the petition fee of \$130.00 as set forth in
37 C.F.R. § 1.17(i) are also enclosed.
- ☐ Charge \$_____ to Deposit Account No. 02-4800 for the fee due.
- ☒ A check in the amount of \$ 210.00 is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: 

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Date: March 14, 1995



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Sir:

In order to ensure compliance with 37 C.F.R. § 1.56, Applicants submit the following additional references which relate to the subject matter of this application. For the convenience of the Examiner, these references are briefly discussed below.

Applications Relating to Expression of
Papillomavirus L1 Proteins

While none of the following applications was published prior to the effective filing date of this application, these applications are cited because there may be U.S. counterparts which claim subject matter related to this application.

WO 94/05792 by Lowy et al, and naming the U.S. Government as Applicant, claims a baculovirus constructs encoding papillomavirus L1 sequence, methods of making L1 proteins by recombinant methods, papillomavirus vaccines containing L1 or L1 and L2 proteins, papillomavirus diagnostic kits and uses thereof. This

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application identifies U.S. applications 07/941,371, filed September 3, 1992 and 08/032,869, filed March 16, 1993.

WO 92/02184 by Frazer et al, and naming The University of Queensland as Applicant, claims methods for making papilloma-viruses VLP's containing L1 or L1 and L2 proteins, VLP's produced by said methods, recombinant viruses containing L1 or L1 and L2 coding sequences, specific DNA fragments and constructs, and methods of ELISA diagnosis of papillomavirus infection. The published application does not identify any U.S. counterparts. However, the PCT application names the U.S. as a designated state. For the convenience of the Examiner, the Australian priority document is also submitted. It should be noted that this priority document does not teach expression of conformationally correct HPV L1 proteins, but rather is limited to the expression of the HPV 16 prototype.

WO 94/20137 by Rose et al, and naming the University of Rochester as the Applicant, is directed to expression of human papillomavirus L1 sequences in recombinant host cells, in particular using a baculovirus expression system. The published application refers to two U.S. applications, 08/028,517, filed March 9, 1993 and 08/207,309, filed March 7, 1994.

Reference Relating to Papillomavirus Vaccines

Pfister, Herbert, "Papillomaviruses and Human Cancer", CRC Press, Chapters 11-12, pp. 225-251 (1991), relates to papilloma-virus diagnostics and prospects for human papillomaviral vaccines.

References Relating to the Expression of COPV
in the Beagle Dog Animal Model

The following references were published after the filing date. However, they are submitted to the Examiner because they provide additional evidence of the overwhelming acceptance by those expert in the art that the COPV/beagle animal model is a suitable model for predicting the efficacy of HPV vaccines.

Ghim et al, "Papilloma Extracts and Recombinant L1 Protein Protect Completely Against Mucosal Papillomavirus Infection: A Canine Model", Oct. 8-12, 1994, 13th International Papilloma-virus Conference.

International Agency (WHO) for Research on Cancer Press Release, December 15, 1994, "Human Papillomavirus Vaccines and Their Potential Use in the Prevention and Treatment of Cervical Neoplasia". Note the last sentence of the reference wherein it is stated that "a prophylactic vaccine will be available commercially within 3-4 years".

Ghim et al, "Formalin-Inactivated Oral Papilloma Extracts and Recombinant L1 Vaccines Protect Completely Against Mucosal Papillomavirus Infection: A Canine Model", Oct. 8, 1994.

Newsome et al, IBC International Symposium, Veterinary Vaccines, Oct. 27-28, 1994, "Formalin-Inactivated Oral Papilloma Extracts and Recombinant L1 Vaccines Protect Completely Against Mucosal Papillomavirus Infection: A Canine Model".

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References Relating to Expression of HPV L1 Proteins

Gynecologic Oncology, 55, 10-12, 1994, "Recombinant Virus-like Particles Retain Conformational Epitopes of Native Human Papillomaviruses and May Be Useful for Vaccine Development".

Rose et al, J. Gen. Virology, 75, 2075-2079, 1994, "Human papillomavirus (HPV) type 11 recombinant virus-like particles induce the formation of neutralizing antibodies and detect HPV-specific antibodies in human sera".

Christensen et al, J. Gen. Virology, 76, 2271-2276, 1994, "Assembled baculovirus-expressed human papillomavirus type I protein virus-like particles are recognized by neutralizing monoclonal antibodies and induce high titres of neutralizing antibodies".

Hines et al, Gynecologic Oncology, 55, 13-20, 1994, "Role of Conformational Epitopes Expressed by Human Papillomavirus Major Capsid Proteins in the Serologic Detection of Infection and Prophylactic Vaccination".

To assist the Examiner in entering these documents in the record, they are listed in the accompanying form PTO-1449.

Respectfully submitted,

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